F 7 11. (Amended) The isolated cancer peptide of claim 1, further consisting essentially of 1 to about 10 amino acids at the N-terminus of the cancer peptide.

F 8 12. (Amended) The isolated cancer peptide of claim 1, further consisting essentially of 1 to about 5 amino acids at the N-terminus of the cancer peptide.

F 9 13. (Amended) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 54-62 of SEQ ID NO: 4.

E5 F 10 14. (Amended) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 48-62 of SEQ ID NO: 4.

F 11 15. (Amended) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 43-62 of SEQ ID NO: 4.

F 12 16. (Amended) A isolated cancer peptide consisting essentially of amino acids 127-136 of SEQ ID NO: 4 or a functionally equivalent variant thereof, wherein the functionally equivalent variant has at least 85% sequence homology with the cancer peptide, wherein said cancer peptide or functionally equivalent variant is immunologically recognized by antigen specific cytotoxic T lymphocytes.

E6 17 26. (Twice Amended) A composition comprising one or more of the cancer peptides of any of claims 1, 1-8, and 10-16. 1 2 5 6 12

E7 14 28. (Twice Amended) An immunogen comprising one or more of the cancer peptides of any of claims 1, 1-8, and 10-16 alone or in combination with at least one immunostimulatory molecule, wherein the immunogen elicits a response by an antigen specific T lymphocyte.

E8 15 29. (Amended) The immunogen of claim 14, wherein the immunostimulatory molecule is an MHC molecule.

Please add the following new claims:

E9 F 16 67. (New) The isolated cancer peptide of claim 63, wherein the MHC class I molecule is selected from the group consisting of HLA-A31, HLA-A3, HLA-A11, HLA-A33, and HLA-A68.

F 17 68. (New) The isolated cancer peptide of claim 3, wherein the MHC class I molecule is HLA-A31.

F 18 69. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 53 and 55-62 of SEQ ID NO: 4, wherein amino acid 54 of SEQ ID NO: 4 is substituted with a different amino acid.

F 19 70. (New) The isolated cancer peptide of claim 18, wherein the different amino acid is threonine.

F 20 71. (New) The isolated cancer peptide of claim 18, wherein the different amino acid is selected from the group consisting of alanine, isoleucine, valine, and leucine.

F 21 72. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 54-62 of SEQ ID NO: 4 and further consists essentially of an additional amino acid at the N-terminus of the cancer peptide.

F 22 73. (New) The isolated cancer peptide of claim 21, wherein the additional amino acid is valine or threonine.

EG

F 23 74. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 52-62 of SEQ ID NO: 4.

F 24 75. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 51-62 of SEQ ID NO: 4.

F 25 76. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 50-62 of SEQ ID NO: 4.

F 26 77. (New) The isolated cancer peptide of claim 1, wherein the cancer peptide consists essentially of amino acids 49-62 of SEQ ID NO: 4.

27 78. (New) An immunogen comprising one or more of the cancer peptides of any of claims 16-26 alone or in combination with at least one immunostimulatory molecule, wherein the immunogen elicits a response by an antigen specific T lymphocyte.

28 79. (New) The immunogen of claim 78, wherein the immunostimulatory molecule is a MHC molecule.

29 80. (New) The immunogen of claim 79, wherein the MHC molecule is an MHC Class I molecule.

30 81. (New) The immunogen of claim 80, wherein the MHC Class I molecule is selected from the group consisting of HLA-A31, HLA-A3, HLA-A11, HLA-A33, and HLA-A68.

31 82. (New) The immunogen of claim 80, wherein the MHC Class I molecule is HLA-A31.

32 83. (New) The immunogen of claim 29, wherein the MHC molecule is a MHC Class I molecule.

33 84. (New) The immunogen of claim 83, wherein the MHC Class I molecule is selected from the group consisting of HLA-A31, HLA-A3, HLA-A11, HLA-A33, and HLA-A68.

34 85. (New) The immunogen of claim 83, wherein the MHC Class I molecule is HLA-A31.

35 86. (New) A composition comprising one or more of the cancer peptides of any of claims 67-77.
16 26

REMARKS

The Present Invention

The present invention pertains to cancer peptides consisting essentially of amino acids 55-62 or amino acids 127-136 of SEQ ID NO: 4 or a functionally equivalent variant thereof, as well as compositions and immunogens, both of which comprise the cancer peptides.

The Pending Claims

Claims 3, 5-8, 10-16, 26, 28, 29 and 67-86 are currently pending, of which claims 3, 5-8, 10-16 and 67-77 are directed to cancer peptides, claims 26 and 86 are directed to compositions

comprising the cancer peptides, and claims 28, 29 and 78-85 are directed to immunogens comprising the cancer peptides.

The Office Action

The Office has treated the election of Group I, Species C, as an election without traverse. The Office alleges that the application contains "unbranched specifically defined sequences" that do not have corresponding SEQ ID NOs identifying the sequences. The Office has objected to the claims for allegedly being mis-numbered. The drawings have not been accepted for allegedly not having one-inch left and right margins. Claims 3, 5-8, and 26 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 3, 5-8, 26, and 27 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement and for purportedly not demonstrating that Applicants had possession of the claimed invention at the time of filing. Claims 3, 5-8, 26, and 27 have been rejected under 35 U.S.C. § 102 (a) as allegedly anticipated by Chen et al., *Proc. Natl. Acad. Sci. USA* 94: 1914-1918 (1997). Reconsideration of these objections and rejections is hereby requested.

The Amendments to the Specification and Claims

The specification has been amended to recite SEQ ID NOs in accordance with the Sequence Listing after an unbranched specifically defined sequence appears in the specification. The Sequence Listing has been amended, as errors were found in the Sequence Listing submitted September 18, 2001. SEQ ID NO: 4 is now an amino acid sequence, as it was in the Sequence Listing submitted April 30, 2001. Furthermore, SEQ ID NO: 4 has been amended to correct the amino acid at position 43, which was inadvertently submitted as a proline, instead of an arginine. The correction of amino acid 43 in SEQ ID NO: 4 is supported by the specification at, for example, Figure 3A-1. Also, the Sequence Listing has been amended in view of the errors pointed out by the Office in Paper No. 12. Figures 2 and 3A-1 have been amended so that there is a 1-inch margin on the left and on the right. Claims 2-24, 27-49 and 51-69 have been renumbered as claims 1-66, respectively. Claims 1, 2, 4, 9, 17-25 and 30-66 have been canceled as being drawn to non-elected inventions. Claim 27 also has been canceled. Applicants reserve the right to pursue any canceled subject matter in a continuation, continuation-in-part, divisional, or other application. Cancellation of any subject matter should not be construed as abandonment of that subject matter. The term "portion" has been deleted from all pending claims. The term "derivative" has been deleted from all pending claims, except for claims 3 and 16, in which it has been replaced by the term "functionally equivalent variant", which is supported by the specification at, for example,

page 13, lines 10-14. In claims 3 and 16, "functionally equivalent variants" has been further defined to have "at least 85% sequence homology to the cancer peptide", which is supported by the specification at, for instance, page 9, lines 20-27. Claim 3 has been amended to read specifically on amino acids 55-62 of SEQ ID NO: 4. Claim 16 has been amended to read specifically on amino acids 127-136 of SEQ ID NO: 4. Claims 5-8 and 10-15 have been amended to read on claim 3, and claims 10 and 13-16 have been further amended to recite the specific amino acids of SEQ ID NO: 4 of which the cancer peptides essentially consist. Claim 26 has been amended such that it is directed to a composition, as opposed to a pharmaceutical composition. Claims 26 and 28 have been amended to depend on the appropriate claims. Claims 8, 26, 28, and 29 have been amended to use language that is deemed more appropriate by one ordinarily skilled in the art. Claims 67-87 have been added, and claims 67, 68, and 79-85 are supported by the specification at, for example, page 8, lines 21-24, and page 12, lines 22-26, whereas claims 69-77 are supported by the specification in, for instance, Table 7. Claims 78 and 86 are supported by the specification in, for instance, claims 28 and 26, respectively. No new matter has been added by way of these amendments. Separate documents setting forth the precise changes to the specification and claims, as well as the text of all pending claims, are enclosed herewith.

Discussion of the Election of Group I, Species C

The Office contends that, because Applicants allegedly did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. For the record, Applicants would like to point out to the Office the Response to the Restriction Requirement mailed on February 4, 2002, in which Applicants did, in fact, point out the reasons why the Restriction Requirement was improper. Applicants maintain and hereby re-submit that SEQ ID NOs: 39, 26, 45, 15, and 14 are all fragments of SEQ ID NO: 4, while SEQ ID NOs: 34-38, and 41 are all derivatives of SEQ ID NO: 4, such that Species F, G, H, I, J, M, N, O, P, Q, R, and S are all related to Species C, and, therefore, should be examined together inasmuch as there would be no undue burden on the Office to do so. Although the Response to Restriction Requirement mailed May 15, 2002, did not explicitly re-iterate this relationship amongst the above Species, it is improper for the Office to ignore what was submitted in the earlier Response to Restriction Requirement (mailed February 4, 2002). In view of the foregoing, Applicants hereby request that the election of Group I, Species C, be treated as an election with traverse.

Discussion of the Rejection under U.S.C. § 112, second paragraph

Claims 3, 5-8, and 26-27 have been rejected under Section 112, second paragraph, for allegedly being indefinite. Specifically, the Office contends that claims 3, 5-8, and 26 are indefinite for using the term "derivative", while claims 3 and 5-8 are indefinite for using the term "portion". Furthermore, the Office alleges that claims 5-8 and 26 depend on claims that are directed to non-elected inventions. This rejection is traversed for the reasons set forth below.

Applicants point out to the Office that the terms "portion" and "derivative" have been deleted from all pending claims. In claims 3 and 16, the term "derivative" has been replaced with the term "functionally equivalent variant", which is supported by the specification at, for example, page 13, lines 10-14. Functionally equivalent variants are further defined in the claims as having "at least 85% sequence homology to the cancer peptide", which is supported by the specification at, for instance, page 9, lines 20-27. Claims 5-8 and 26 have been amended to depend only on claims directed to elected inventions. In view of these amendments, Applicants submit that claims 3, 5-8, and 26-27 are not indefinite. Therefore, Applicants hereby request that the rejection under Section 112, second paragraph, be withdrawn.

Discussion of the Rejection under U.S.C. § 112, first paragraph

Claims 3, 5-8, 26 and 27 have been rejected under Section 112, first paragraph, for allegedly lacking enablement for "portions and derivatives of SEQ ID NO: 4". In particular, the Office states that the specification does not give any guidance as to which portions or derivatives of SEQ ID NO: 4 exhibit the biological activities as claimed, any guidance as to which regions of amino acid sequence are responsible for biological activity and should be preserved, and any guidance as to which derivatives can function similarly to the peptides. This rejection is traversed for the reasons set forth below.

Applicants point out to the Office Tables 4 and 5, which describe those portions of the amino acid sequence of CAG-3 that were screened and scored for potential binding to the MHC molecule, HLA-A31, based on pre-determined putative binding motifs for this particular MHC molecule. Furthermore, Table 6 describes different portions of SEQ ID NO: 4 that were tested for the ability to elicit a cytotoxic T lymphocyte (CTL)-mediated immune response, as indicated by granulocyte macrophage-colony stimulating factor (GM-CSF) release. Moreover, Table 7 describes the analysis of various derivatives of the portion of SEQ ID NO: 4 comprising the amino acid sequence GPGGGAPR (amino acids 55-62), wherein the derivatives further consist of additional amino acids at the N-terminus of the peptide and/or contain a single amino acid substitution, for the ability to

induce a CTL-mediated immune response. Additionally, the specification teaches how to make and use the present inventive cancer peptides at, for instance, page 13, lines 15-26, and at, for example, page 14, line 18, through page 15, line 1.

Applicants point out that the pending claims have been amended to recite the specific portions of SEQ ID NO: 4 of which the cancer peptides essentially consist. For example, claim 3 recites "a cancer peptide consisting essentially of amino acids 55-62 of SEQ ID NO: 4." The portions of SEQ ID NO: 4 to which the pending claims are directed are supported by the specification in, for example, Tables 4-7. The pending claims also have been amended such that the claims no longer recite the term "derivative." Claims 3 and 16 now recite "functionally equivalent variants" which is supported by the specification at, for example, page 13, lines 10-14. The functionally equivalent variants of Table 7 are the subject matter of claims 10-15 and 69-77.

In view of the foregoing, Applicants submit that the specification is replete with guidance as to which portions and functionally equivalent variants of SEQ ID NO: 4 exhibit the desired biological activity. Applicants further submit that the specification also teaches how to make and use these portions and variants. Therefore, Applicants submit that the present inventive cancer peptides are enabled and request that the rejection under Section 112, first paragraph, for alleged lack of enablement be withdrawn.

Claims 3, 5-8, 26 and 27 have been rejected for allegedly lacking a written description in such full, clear, concise, and exact terms or in sufficient detail such that one of ordinary skill in the art would reasonably conclude that the Applicants had possession of the claimed invention at the time of filing. Specifically, the Office contends that, although the specification discloses the invention as a cancer peptide of SEQ ID NO: 4 and derivatives thereof that share partial sequence homology with SEQ ID NO: 4, the specification lacks a sufficient written description of *derivatives* of SEQ ID NO: 4 (emphasis added). This rejection is traversed for the reasons set forth below.

Applicants point out to the Office that all of the pending claims have been amended to read on cancer peptides consisting essentially of amino acids 55-62 of SEQ ID NO: 4 or amino acids 127-136 of SEQ ID NO: 4, both of which were analyzed for the ability to bind to HLA-A31 (see Table 4) and tested for the ability to stimulate CTLs (see Table 6). Functionally equivalent variants of the cancer peptide consisting essentially of amino acids 55-62, to which claims 10-15, 69-77 are directed, were also tested for the ability to stimulate CTLs (see Table 7). Furthermore, compositions comprising these cancer peptides are described in the specification at, for example, page 13, line 27, through page 14, line 12. Moreover, the term "derivative" has been deleted from all pending claims.

In view of the above, Applicants submit that the specification is replete with written description of the invention of the amended claims, such that one ordinarily skilled in the art would reasonably conclude that Applicants had possession of the invention at the time of filing. Therefore, Applicants request that the rejection under Section 112, first paragraph, be withdrawn.

Discussion of the Rejection under U.S.C. § 102(a)

Claims 3, 5-8, 26 and 27 have been rejected under Section 102(a) for allegedly being anticipated by Chen et al., *Proc. Natl. Acad. Sci USA* 94: 1914-1918 (1997). This rejection is traversed for the reasons set forth below.

Applicants point out to the Office that all of the pending claims have been amended to read on specific parts of SEQ ID NO: 4, namely amino acids 55-62 or amino acids 127-136. Although SEQ ID NO: 4 is disclosed in Chen et al., this reference neither teaches nor suggests the particular regions of this amino acid sequence that are particularly effective at eliciting a CTL-mediated response. Chen et al., furthermore, discloses that it was unknown as to whether or not NY-ESO-1 induced a CTL-mediated response, as it states: "it will be of interest to investigate the possible CD8 T cell response against NY-ESO-1."

In view of the foregoing, Applicants submit that Chen et al. does not anticipate the instantly rejected claims. Therefore, Applicants hereby request that the rejection under Section 102(a) be withdrawn.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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